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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,954	06/09/2005	Steven Glazer	0256.210US	6912
30560	7590	10/05/2007		
MAXYGEN, INC. INTELLECTUAL PROPERTY DEPARTMENT 515 GALVESTON DRIVE REDWOOD CITY, CA 94063			EXAMINER HISSONG, BRUCE D	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 10/05/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/506,954	Applicant(s) GLAZER ET AL.	
	Examiner Bruce D. Hissong, Ph.D.	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 8-45 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>sequence comparison</u> .              |

**DETAILED ACTION*****Election/Restrictions*****A. Restriction is required under 35 U.S.C. 121 and 372.**

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The claims of the instant invention are drawn to methods of treating or preventing stroke or cerebrovascular accident or transient ischemic attack in a primate, said methods comprising administering an interferon (IFN)- $\beta$  polypeptide variant comprising an amino acid sequence in which at least one glycosylation site has been introduced. It is noted that the claims are drawn to examination of at least one of a number of structurally distinct IFN- $\beta$  variants comprising various amino acid residue substitution, including various substitution for lysine residues. The claims are also drawn to IFN- $\beta$  variants comprising various combinations of substitutions, including the combinations recited in claim 37.

In order to be fully responsive, applicant is required to further restrict a specific combination of amino acid substitutions recited in claim 37. This is NOT an election of species. The claimed IFN- $\beta$  variants are structurally distinct chemical compounds by virtue of having different primary amino acid sequences, and are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such variant is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141. By statute "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant.....to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a). It is noted that search more than one of the claimed patentably distinct variant combinations represents a serious burden for the office. Furthermore, it is noted that the claims will be searched with respect to the

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elected combination of substitutions. For example, if Applicants elect the combination of substitutions represented by C17S + Q49A + Q51T + K19R + K33R + K45R, then all claims reciting this combination will also be searched.

**B.** The claimed invention of the instant application does not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The first claimed invention fails to share a special technical feature with the other claims. PCT rules define a special technical feature as a feature that makes a contribution over the art. Independent claims 39 and 44 have no such special technical feature in view of Shirley *et al* (US 6,887,462). Independent claims 39 and 44 are drawn to methods of treating or preventing stroke or cerebrovascular accident or transient ischemic attack in a primate, said methods comprising administering an interferon (IFN)- $\beta$  polypeptide variant comprising an amino acid sequence in which at least one glycosylation site has been introduced. Shirley *et al* teaches administration of IFN- $\beta$  polypeptides, including a sequence identical to SEQ ID NO: 2 of the instant application (see sequence comparison) for various disorders, including cerebrovascular disorders (column 16, lines 15-41, and specifically line 30). Shirley *et al* also teaches that the IFN- $\beta$  polypeptides can be modified by various methods known in the art, such as incorporation of substitutions, and include IFN- $\beta$  polypeptides that are glycosylated (column 9, line 48 – column 11, line 4, and specifically column 9, line 62). Thus, because Shirley *et al* teaches administration of IFN- $\beta$  polypeptides that can be modified by substitutions, which could include substitutions allowing for introduction of glycosylation sites, wherein said administration is to individuals suffering cerebrovascular disorders, the methods recited in claims 39 and 44 do not represent a contribution over the prior art.

**C.** Applicant is also advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**D.** Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named

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inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

E. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bruce D. Hissong  
Art Unit 1646

/Robert S. Landsman/  
Primary Examiner, Art Unit 1647

SEQUENCE COMPARISON 10/506,954

RESULT 7

US-10-035-397-1

; Sequence 1, Application US/10035397

; Patent No. 6887462

; GENERAL INFORMATION:

; APPLICANT: Shirley, Bret A.

; APPLICANT: Babuka, Susan

; APPLICANT: Chen, Bao-Lu

; APPLICANT: Hora, Maninder

; APPLICANT: Choe, Minna

; APPLICANT: Tellers, Melanie

; TITLE OF INVENTION: HSA-Free Formulations of Interferon-Beta

; FILE REFERENCE: PP17201.003

; CURRENT APPLICATION NUMBER: US/10/035,397

; CURRENT FILING DATE: 2001-10-25

; PRIOR APPLICATION NUMBER: 60/330,404

; PRIOR FILING DATE: 2001-10-18

; PRIOR APPLICATION NUMBER: 60/282,614

; PRIOR FILING DATE: 2001-04-09

; NUMBER OF SEQ ID NOS: 2

; SOFTWARE: FastSEQ for Windows Version 4.0

; SEQ ID NO 1

; LENGTH: 166

; TYPE: PRT

; ORGANISM: Homo sapiens

US-10-035-397-1

Query Match 100.0%; Score 874; DB 2; Length 166;

Best Local Similarity 100.0%; Pred. No. 1.1e-84;

Matches 166; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy      1 MSYNLLGFLQRSSNFQCQKLLWQLNGRLEYCLKDRMNFDIPEEIKQLQQFQKEDAALTIY 60
          |||
Db      1 MSYNLLGFLQRSSNFQCQKLLWQLNGRLEYCLKDRMNFDIPEEIKQLQQFQKEDAALTIY 60

Qy      61 EMLQNIFAIFRQDSSSTGWNETIVENLLANVYHQINHLKTVLEEKLEKEDFTRGKLMSSL 120
          |||
Db      61 EMLQNIFAIFRQDSSSTGWNETIVENLLANVYHQINHLKTVLEEKLEKEDFTRGKLMSSL 120

Qy      121 HLKRYYGRILHYLKAKEYSHCAWTIVRVEILRNFYFINRLTGYL RN 166
          |||
Db      121 HLKRYYGRILHYLKAKEYSHCAWTIVRVEILRNFYFINRLTGYL RN 166
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